

)	MDL No. 1456
In re: PHARMACEUTICAL INDUSTRY)	Master File No. 01-12257-PBS
AVERAGE WHOLESALE PRICE LITIGATION)	Subcategory Case No. 06-11337
)	
)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO:)	
)	
<i>State of California ex rel. Ven-A-Care of the Florida</i>)	
<i>Keys, Inc. v. Abbott Labs, Inc. et al.,</i>)	
Civil Action No. 03-11226-PBS)	
)	

PRELIMINARY STATEMENT

As to *scienter*, Plaintiffs have failed to adduce any evidence that Defendants understood that California expected them to report AWP's that approximated actual acquisition costs, or that Defendants believed or should have believed that they were providing false or misleading information when they reported their AWP's. By contrast, the record is replete with evidence demonstrating that Defendants reported their actual invoice prices to pricing compendia for publication, provided fully discounted net prices – federally defined AMPs – directly to the Medicaid program at the federal level, and paid rebates calculated from those AMP prices directly to California. The record also shows Defendants' repeated communications with California in which California made it clear that it did *not* expect AWP's to approximate actual

acquisition cost, as it now contends. Plaintiffs have no answer to this evidence. Plaintiffs' argument that Defendants should have surmised that they were expected to report AWP that approximated actual cost is legally and factually unsupported, including being contradicted by the statutes and regulations that they cite to support it.

As to causation, Plaintiffs have no answer to the evidence in the record showing that California was well aware since before the relevant time period that AWP significantly exceeded providers' actual acquisition costs for generic drugs, but nonetheless embraced AWP in its reimbursement calculations to ensure that Medi-Cal beneficiaries had adequate access to quality medical care, as required by the Ninth Circuit's decision in *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997). These deliberate policy decisions by California break the causal link between Defendants' conduct and the alleged "false claims." Plaintiffs offer no basis in the record to support their speculative contention that, as a matter of law, California always would have paid less had Defendants reported Prof. Leitzinger's "but for" prices. Nor could they, since evidence in the record, most notably the current Ninth Circuit injunction barring California from lowering its pharmacy reimbursement rate, flatly refutes this claim.

A reasonable reading of the statutes, regulations, and regulatory record upon which Plaintiffs base their falsity argument actually demonstrates that California did not understand or intend AWP to be actual approximations of providers' costs.

Finally, Plaintiffs improperly ask the Court to grant summary judgment on a "government knowledge defense," while ignoring that "government knowledge" evidence is not offered by Defendants to prove an affirmative defense but, rather, negates elements of Plaintiffs' underlying claims on which Plaintiffs bear the burden of proof. In any event, even if

“government knowledge” is an affirmative defense, the record contains sufficient evidence to at the very least create issues of fact requiring denial of California’s motion on this issue.

ARGUMENT

I. PLAINTIFFS HAVE NOT ESTABLISHED *SCIENTER* AS A MATTER OF LAW

A. Plaintiffs Have Failed to Adduce Any Evidence of *Scienter* or Rebut Defendants’ Evidence Showing a Lack of *Scienter*

Summary judgment on *scienter* is inappropriate on the record here. The “knowingly” element of a False Claims Act claim is a fact intensive question that is normally reserved for the jury. *See United States ex rel. Koch v. Koch Industries, Inc.*, 57 F.Supp.2d 1122, 1130 (N.D. Okla. 1999) (“[T]he ‘knowingly’ prong of the FCA is one of fact, and should be decided by the finder of fact at trial and not prematurely decided on summary judgment.”). Plaintiffs have failed to adduce any factual evidence that Defendants knew or understood that the AWP for the Subject Drugs published in the pricing compendia were in any way inconsistent with California’s expectations or industry understanding.

In contrast, Defendants have put substantial evidence into this record that they each understood that AWP was an undiscounted benchmark price, which, for generic drugs, was set in relation to published AWP for therapeutically equivalent products. *See* Joint Opp. at 26-30.¹ The evidence of each Defendant’s own conduct undermines any claim that it knowingly provided California with false information. Each Defendant reported its invoice prices to wholesalers as its WACs to compendia for publication. *Id.* Each Defendant complied with its obligations under its federal Rebate Agreement by reporting AMPs – the “net prices to wholesalers and distributors” that take into account discounts, rebates, chargebacks and any other price adjustments – to CMS on a quarterly basis and paying rebates directly to California based

¹ “Joint Opp.” or “Defendants’ Joint Opposition Brief” refers to Defendant’s Joint Brief in Opposition to Plaintiffs’ Motion for Partial Summary Judgment, dated Dec. 21, 2009 (Dkt. No. 6801).

on those AMPs. *Id.* Sandoz voluntarily reported AMPs directly to Medi-Cal from 1991 to 1997. *See* Joint Opp. at 27.² Dey’s WACs routinely declined over time as competition pushed Dey’s transaction prices lower. *See* Joint Opp. at 30. Additionally, in 1999, Dey began disclosing to California that it set its AWP before any drugs were sold and that its AWP was not a price that was paid or charged for its drugs. *See* Joint Opp. at 29-30. In 1992, representatives of Mylan met with Medi-Cal officials, urging them to adopt tighter MAC controls. At the meeting, the Mylan representatives compared Medi-Cal’s reimbursement payments (which were based on AWP minus 5 percent at the time) to payments made under Ohio’s MAC program to demonstrate the “substantial savings” Medi-Cal could achieve. *See* Palermo Decl. Ex. W. at ¶ 95; Robben Decl. Ex. 62 at CAMYLAN04092024.³ In 2002, a Medi-Cal employee sent Eric Belldina at Mylan an e-mail indicating that California fully expected “spreads” of 500 percent between published AWP and reported AMP for generic drugs. *See* Joint Opp. at 28-29. In short, the evidence shows that Defendants were publicly disclosing the invoice prices for their drugs and reporting averages of the final net prices for their drugs to the Medicaid program and that direct communications between California and Defendants confirm that California did not expect published AWP to approximate actual acquisition cost. Thus, the notion that Defendants “knowingly” caused the submission of false claims is simply untenable.

California counters Defendants’ evidence negating *scienter* by arguing that it was not required to investigate the disclosures made by Defendants, or that its communications with Defendants did not demonstrate its “approval” of Defendants’ conduct. These arguments miss

² Indeed, Sandoz’ representatives attended numerous meetings with officials from Medi-Cal and believed that those officials all understood that AWP was not an actual average. *See* Sandoz’ Resp. to Pls.’ SOF ¶ 6.

³ “Palermo Decl.” refers to the Declaration of Christopher C. Palermo in Support of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.’s Opposition to Plaintiffs’ Motion for Partial Summary Judgment, dated Dec. 21, 2009, and the exhibits annexed thereto; “Robben Decl.” refers to the Declaration of Philip D. Robben in Support of Defendants’ Joint Sur-Reply Brief in Opposition to Plaintiffs’ Motion for Partial Summary Judgment, dated Jan. 29, 2010, and the exhibits annexed thereto.

the mark because they concern California's conduct and knowledge. The relevant question on *scienter*, however, is whether Defendants understood that they were providing false information or causing the submission of false claims. In short, this evidence at the very least creates questions of fact as to Defendants' *scienter* and is more than sufficient to preclude summary judgment in Plaintiffs' favor.

B. Plaintiffs' "Plain Meaning" *Scienter* Argument Fails for the Same Reason Their Falsity Argument Fails

Rather than offer any evidence of Defendants' *scienter*, Plaintiffs' contend that *scienter* can be shown by reference to the same false premise upon which their falsity arguments rest, namely that a 1989 regulation governing Medi-Cal's reimbursement methodology for most of the relevant time period employed AWP in a manner that Defendants should have realized that California intended AWP to approximate a provider's actual cost to acquire a drug. *See, infra*, Point III. This *scienter* argument fails.

Plaintiffs have failed to cite to any authority that would support a finding of *scienter* under the CFCA based solely on a defendant's failure to properly interpret a statute or regulation that does not directly govern the defendant's conduct. Plaintiff cites *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51 (1984) and *United States v. Mackby*, 261 F.3d 821 (9th Cir. 2001) to argue that Defendants should have been aware that California intended AWP to represent actual acquisition cost. Neither of these cases are on point. In *Heckler*, which was not a FCA case at all, a Medicare provider submitted claims for Medicare reimbursement that did not deduct federal grant money that the provider had received as part of a separate federal program. 467 U.S. at 56. The Supreme Court held that the federal government was not equitably estopped from seeking to recover the amount of the grant money from the Medicare reimbursement payments it made to the provider – despite the fact that a Medicare

fiscal intermediary informed the provider that he could include the amount of the grants in his reimbursement claim – in part because the regulation governing the grants explicitly required that the grants be deducted from any reimbursement claim submitted by providers. *Id.* at 64.

In *Mackby*, the owner of a physical therapy clinic was found liable under the FCA for submitting Medicare reimbursement claim forms for services performed at the clinic that included the Provider Identification Number (“PIN”) for a doctor who did not perform the services and was not affiliated with the clinic. 261 F.3d at 825. The Ninth Circuit held that the owner’s failure to read the regulations and guidelines governing the submission of claims Medicare program, which explicitly required that provider include the PIN for the physician who supplied the services on the reimbursement claim form, was not sufficient to negate *scienter*. *Id.* at 828.

At best, these cases stand for the proposition that a party cannot plead ignorance of explicit terms in a statute that directly govern his or her conduct. They do not stand for the proposition that drug manufacturers like Defendants were required to draw certain unwritten inferences from statutes and regulations not even directed to them, much less that Defendants’ failure to do so supports a finding of *scienter* as a matter of law under the CFCA.

In fact, the only reasonable conclusion Defendants could draw from reading the regulations and statutes governing Medi-Cal pharmacy reimbursement is that California did not expect or intend AWP to approximate actual acquisition cost. AWP is not defined in California’s statutes and regulations as anything other than a price listed in compendia. The regulation from which Plaintiffs contend that Defendants should have gleaned the meaning of AWP California now advances calls for reimbursement payments based on AWP *less* a certain discount (first, of five percent, then in 2002 of ten percent and in 2004 of 17 percent.) It also

calls for reimbursement payments based on FULs, MAICs, or the provider's usual and customary charge, when those benchmarks result in reimbursement payments lower than AWP minus five percent. If, in fact, California had intended AWP to approximate providers' actual costs, then one would have expected California to have said so and to have expressly defined AWP as such. California did not do so. Likewise, if California had understood AWP to represent actual acquisition cost, California would have set reimbursement at an undiscounted AWP, not at a discounted AWP or other benchmarks designed to drive reimbursement below a discounted AWP.⁴

Moreover, if Defendants had reviewed California's regulations and statutes in conjunction with the federal regulations governing Medicaid reimbursement, they would have expected Medi-Cal's reimbursement methodology to approximate providers' costs in the aggregate, not on a drug-by-drug basis, and that California expected that its AWP-based payments would result in margins above providers' costs for generic drugs. *See* Opp. Brief at 8-10. In short, had Defendants reviewed California's reimbursement methodology, the only reasonable conclusion they would have reached is that California did *not* expect AWP to approximate actual ingredient acquisition cost and instead intended to pay providers at above their costs.

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Indeed, California could not have meant for Defendants' reported AWP to equal providers' acquisition costs, discounted those same AWP, and still have met federal requirements for economy, efficiency, and access to care, because to do so would have meant that California was discounting actual acquisition cost. Considering that the evidence also demonstrates that California was under-paying on dispensing fees, California would then have also been under-paying providers on acquisition costs, resulting in a significant shortfall that would have certainly driven providers from the program, thus failing the federal mandate.

II. PLAINTIFFS HAVE FAILED TO ESTABLISH THE CAUSAL LINK BETWEEN DEFENDANTS' CONDUCT AND THE ALLEGED "FALSE CLAIMS"

A. California's Informed Policy Choices Break the Causal Link

Plaintiffs have no answer to the evidence Defendants set forth in their opposition briefing showing that California knowingly adopted and maintained a reimbursement methodology based in part on AWP to ensure that Medi-Cal beneficiaries have adequate access to medical care, as required by the Ninth Circuit's decision in *Orthopaedic Hospital*. Instead, Plaintiffs attempt to recast this argument as a "government knowledge" argument and regurgitate the same flawed arguments that they put forth to support summary judgment on the "government knowledge defense." *See, infra*, Pt. IV. Plaintiffs' tactic misses the mark. What breaks the causal link between Defendants' alleged conduct and the alleged "false claims" is not merely California's understanding and expectation that AWP significantly exceeds acquisition costs for generic drugs, but also the reality that California embraced AWP as part of its lower-of formula because it was concerned that, without this element, lower reimbursement payments would drive providers from the Medi-Cal program, impair beneficiaries' access to care, and imperil the whole program.

In 1997, 1999, and 2000, Medi-Cal officials considered reductions in reimbursement payments, knowing that Medi-Cal's lower-of formula paid providers considerable margins above their costs to acquire generic drugs. Joint SOF at ¶¶ 33, 35, 36.⁵ Yet these reductions were never adopted because of access concerns. *Id.* In 2002, when California did finally reduce its reimbursement rate to AWP minus ten percent, it considered setting reimbursement for generic drugs (*i.e.* the types of drugs at issue in this action) at AWP minus 40 percent, knowing that providers could purchase generic drugs at 40 to 50 percent below AWP. Joint SOF at ¶¶ 52, 53.

⁵ "Joint SOF" refers to the Defendants' Joint Statement of Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment, dated November 25, 2009 (Dkt. No. 6703).

California ultimately rejected the proposal, however, because many pharmacists stated that the reduced rates would force them to stop participating in the program. *Id.* In 2004, two years after the Myers and Stauffer report documented for California large percentage spreads – sometimes in excess of 1000 percent – for 77 of the Subject Drugs, California chose to set reimbursement at AWP minus 17 percent and increased dispensing fees. Joint SOF at ¶¶ 45, 54-59. Most recently, in 2009, Kevin Gorospe, the current Chief of the Medi-Cal Pharmacy Policy submitted an affidavit supporting a five percent reduction in pharmacy reimbursement payments on the grounds that the ingredient cost portion of California’s reimbursement methodology, which still uses AWP minus 17 percent as one possible basis, “is well above pharmacy acquisition cost” and “that any loss on the dispensing fee portion of reimbursement is made up for by a significant profit on Medi-Cal reimbursement for the drug itself.” *See* Joint SOF at ¶ 67. Despite that affidavit, the United States District Court for the Eastern District of California granted the reduction because of Medi-Cal’s failure to show that access would not be impaired. *See* Joint SOF at ¶ 68.

Plaintiffs attempt to recast California’s conduct as “ameliorative efforts” that were necessary in response to Defendants’ price reporting practices. However, they cannot cite to any factual evidence in the record to support this argument. Moreover, if it was, in fact, California’s goal to only ever pay providers their actual acquisition cost for drugs, then California bizarrely never took the most logical “ameliorative” step, which would have been to define AWP in a statute or regulation in the manner they assert for the first time in this litigation. Given that Plaintiffs have conceded elsewhere in their briefing that Defendants’ price reporting practices were consistent with “widespread ... industry practice” (CA Joint Opp. Brief at 3)⁶, California’s

⁶ “CA Joint Opp. Brief” refers to Plaintiffs’ Opposition to Defendants’ Joint Brief in Support of Their Motions for Partial Summary Judgment, dated December 21, 2009 (Dkt. No. 6789).

failure to provide any guidance regarding how manufacturers should set their AWP, coupled with the fact that it knowingly paid large percentage spreads for generic drugs is sufficient, at the very least, to raise questions of fact as to the “cause” of what Plaintiffs now contend were “false claims.”

B. Plaintiffs Have Failed to Demonstrate That California Would Have Paid Less Than FUL for the Subject Drugs

Plaintiffs do not dispute that CMS officials departed from the rigid formula set forth in the federal regulations governing the calculation of FULs and that Defendants had no control over the manner in which FULs were ultimately set.⁷ Instead, Plaintiffs insist that, if Defendants had reported the “but for” AWP calculated by Prof. Leitzinger, California always would have reimbursed providers based on those AWP, rather than the FULs set by CMS. However, this claim is utterly unsupported by the actual record which shows over and over again that California would not have accepted these lower prices.

During the relevant time period, California itself was reluctant to make even modest reductions to its reimbursement payments out of concern that the reductions would have impaired access. Joint SOF at ¶¶ 33, 35, 36, 52, 53. Most notably, California is currently enjoined from implementing a five percent reduction in its reimbursement payments because of

⁷ Defendants note that the MDL Court has recently issued a decision finding liability against defendant drug manufacturers on so-called “FUL fraud” claims brought by various counties in New York State. *See In re Pharm. Indus. Average Wholesale Price Litig.*, No 01-12257, ___ F. Supp. 2d ___, Slip Op. at 30 (D. Mass. Jan. 27, 2009). However, that holding is inapplicable to California’s claims for drugs paid on the basis of FUL. In that decision, the MDL Court held that the defendants were liable under a New York State statute for claims paid on the basis of FULs for nine drugs, where the FUL prices were set based on allegedly inflated Wholesale Acquisition Cost (“WAC”) prices for those nine drugs. *Id.* at 17-18. Unlike California’s “lower of” reimbursement methodology, the New York Counties would always reimburse at FUL when a drug had a FUL. *Id.* at 13. In contrast, California has failed to adduce any evidence related to the setting FULs for any of the Subject Drugs in this action and instead simply contends, despite the factual record to the contrary, that it would have always paid Prof. Leitzinger’s “but for” prices if Defendants reported them as AWP. Further, in this case, the regulatory history surrounding California’s incorporation of FULs into its reimbursement formula in 1987 shows that California was fully aware of actual transaction prices in the marketplace, the “spread” between generic AWP and actual acquisition costs for pharmacies in California, and the savings it would obtain from increased generic substitution. *See* Joint SOF at ¶ 26.

the adverse impact on Medi-Cal beneficiaries' access to care. Joint SOF at ¶¶ 65-68. In light of this evidence, there is at least a question of fact as to whether the prices reported by Defendants would have had any impact on the reimbursement claims California paid on the basis of a FUL (or, for that matter, any of the other claims at issue).

C. **Plaintiffs' Post Hoc, Self-Serving Interpretations of The Regulations and Statutes Governing Medi-Cal Reimbursement Do Not Establish a Causal Link**

Finally, Plaintiffs contend that, despite the fact that Defendants have no control over the manner in which California sets its reimbursement rate and that California has never issued any statute or regulation governing how Defendants should set AWP, a causal link nonetheless exists between Defendants' conduct and the alleged "false claims" because Defendants had an obligation to familiarize themselves with California's reimbursement methodologies. To support this point, Plaintiffs cite to the same authority – *Heckler* and *Mackby* – they cited to support their argument that Defendants' *scienter* is supported by their failure to figure out California's alleged understanding of AWP from the reimbursement regulations. These authorities are no more help to California's causation argument than they are to California's *scienter* argument. As noted above, *Heckler* stands for the proposition that statements made by a fiscal intermediary that contradict express terms in a regulation were not sufficient to estop the federal government from seeking to recover overpayments. 467 U.S. at 64. *Mackby* stands for the proposition that a provider's failure to review the regulations and guidelines governing the reimbursement claims he submitted to the Medicare program was not sufficient to negate *scienter* under the FCA. 261 F.3d at 828. Neither of these cases stands for the principle that Defendants' failure to draw certain inferences from statutes and regulations that do not directly govern Defendants' conduct at all could somehow establish causation under the CFCA as a matter of law.

III. PLAINTIFFS HAVE NOT ESTABLISHED FALSITY AS A MATTER OF LAW AND UNDISPUTED FACT

Plaintiffs have not established falsity in this action as a matter of law because there are disputed factual issues regarding whether Defendants submitted false AWP *as defined by California's own regulations*. Indeed, California's reimbursement regulation simply states that AWP is "the price for a drug product ... listed for a standard package in the Department's primary price reference source." CAL. CODE. REGS. tit. 22 § 51513 (a)(7) (1989). The regulation further gives the Director of Medi-Cal the authority and responsibility to choose an appropriate pricing compendium based on several enumerated factors. Based on the language in California's own regulations and statutes, AWP is defined as the price listed in the pricing compendia that the Director of Medi-Cal selects after review.

California's regulatory (and subsequently statutory) definition of AWP, therefore, simply adopted the industry practice in place in 1989, whereby Defendants would report AWP to national pricing compendia, as had been the practice for years. California's regulations offered absolutely no guidance as to what standard, if any, California expected AWP to meet. There was certainly nothing in California's circular definition to suggest that Defendants' AWP was required to meet a certain standard or a particular price other than what is reported to the pricing compendia. Defendants' practice is the reasonable interpretation of the term AWP as it was defined by California in the 1989 regulation, and it comports with the same definition in use by the State today. This interpretation of AWP does not, as Plaintiffs contend, invite opportunities for unrestrained AWP inflation. *See* Plaintiffs' Reply at 13; *see also* Mylan's Opp. to Pls.' SOF at ¶¶ 6-8; Dey's Opp. to Pls.' SOF at ¶¶ 8-9; Sandoz' Resp. to Pls.' SOF at ¶¶ 8-9 (explaining

Defendants’ basis for setting AWP).⁸ Because a genuine issue of material fact still exists regarding, *inter alia*, the pricing compendia’s use of AWP, summary judgment is inappropriate on these grounds and California’s motion must be denied.

Plaintiffs’ argument that AWP should have equaled an actual average of acquisition costs is belied by its own regulations and actions, which clearly demonstrate that California did not expect or intend AWP to meet this definition, raised for the first time in this litigation. In fact, by discounting from AWP in its Estimated Acquisition Cost (EAC) formula (AWP-5% in the 1989 regulations and then to AWP-10% and AWP-17% in subsequent statutory changes), Medi-Cal and the California legislature continually acknowledged that AWP was not an actual approximation of wholesale prices. Nevertheless, California embraced AWP as one possible benchmark in Medi-Cal’s reimbursement formula to ensure that pharmacy reimbursement payments met the federal requirements of efficiency, economy, and access to care. Indeed, the evidence shows that California knew for decades through its communications with CMS – and through its own California-specific studies – that AWP was not an actual average price and acted accordingly by routinely setting reimbursement rates at a percentage off of AWP in an attempt to satisfy the State’s policy goals. *See* Joint SOF at ¶¶ 22-32, 41-54.

The Final Statement of Reasons accompanying California’s adoption of AWP minus five percent as one possible reimbursement basis defeats any notion that California intended its reimbursement payments to approximate actual cost on a drug-by-drug basis. The Final

⁸ “Plaintiffs’ Reply” refers to Plaintiffs’ Reply Brief in Support of Motion for Partial Summary Judgment, dated Jan. 15, 2010 (Dkt. No. 6842); “Mylan’s Opp. to Pls.’ SOF” refers to Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.’s Individual Local Rule 56.1 Statement in Opposition to Plaintiffs’ Local Rule 56.1 Statement of Undisputed Material Facts as to the Mylan Defendants, dated Dec. 21, 2009 (Dkt. No. 6800); “Dey’s Opp. to Pls.’ SOF” refers to Defendants Dey, L.P. and Dey, Inc.’s Individual Local Rule 56.1 Statement in Opposition to Plaintiffs’ Local Rule 56.1 Statement of Undisputed Material Facts as to the Dey Defendants, dated Dec. 21, 2009 (Dkt. No. 6795); “Sandoz’ Resp. to Pls.’ SOF” refers to Defendant Sandoz Inc.’s Response to Plaintiffs’ Local Rule 56.1 Statement of Undisputed Facts as to Sandoz Inc., dated Dec. 21, 2009.

Statement of Reasons shows that rulemakers arrived at the AWP minus five percent formula not because it was the best estimate of acquisition costs as Plaintiffs now claim, but because California policy makers decided it was an appropriate *compromise* between the goals of economy and access. *See* Robben Decl., Ex. 63 (noting that AWP minus five percent presented “the greatest savings with the least disruption to the Medi-Cal drug distribution system.”); *see also* Robben Decl., Ex. 64. Medi-Cal knew in 1989 that actual average acquisition costs of branded drugs for providers were closer to AWP minus 13.9 percent. *See* Robben Decl., Ex. 65.⁹ However, Medi-Cal did not lower the EAC formula commensurately because the Department knew that it could achieve *aggregate* savings of AWP minus 12 percent when it considered all ingredient reimbursement limits (including FAC and MAIC) as a whole.¹⁰ *See id.* Furthermore, Medi-Cal was aware that any attempt to lower EAC beyond AWP minus five percent could cause providers to leave the program. *See* Robben Decl., Ex. 66.¹¹ The record shows that multiple and often competing considerations went into Medi-Cal’s derivation of the AWP minus five percent formula. It was not simply, as Plaintiffs now claim, Medi-Cal’s closest approximation of actual average acquisition cost.¹²

Relying on what they claim to be an “undefined” term in California’s regulations and statutes, Plaintiffs also ask this Court to apply the same “plain meaning” definition of AWP that the MDL Court adopted in the Medicare class action litigation. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 287 (D. Mass. 2006). Plaintiffs fail to

⁹ Attachment F to the Addendum to Final Statement of Reasons (R-72-89).

¹⁰ Defendants have cited extensive evidence that California had knowledge of actual average prices and the margin between these prices and AWP when it adopted its FUL regulations in 1987. *See* Joint SOF at ¶ 26.

¹¹ Attachment G to the Addendum to Final Statement of Reasons (R-72-89).

¹² As noted in Defendants’ Joint Opposition Brief, the federal regulations governing Medicaid pharmacy reimbursement rates do not require reimbursement payments to approximate actual cost on claim-by-claim, drug-by-drug basis, and actual contemplate paying margins above cost for generic drugs such as the Subject Drugs.

acknowledge, however, that the MDL Court’s plain meaning construction of AWP was limited to the specific context of that case, which focused on a different federal statute. *See* Joint Opp. at 21-22. The Court relied on a plain meaning approach in the prior instance because there was no explicit definition of AWP on the face of the statute. *See* 42 U.S.C. § 1395u(o) (1998). In contrast, California’s statutes and regulations define AWP as the price for a drug product listed in the chosen pricing compendia. The Court cannot adopt an interpretation of AWP as used in a federal Medicare statute when California has defined AWP in a different way in its Medicaid statutes and regulations.¹³ California cannot retroactively delete portions of its regulations and statutes to fit its litigation strategy.

In sum, AWP, as defined in the California regulation, is the same AWP that Defendants report to the pricing compendia. This reasonable interpretation of AWP not only comports with the law, but also with California’s own actions towards AWP and long-held understanding of the way AWP is used in the pharmaceutical industry. Plaintiffs simply cannot establish falsity as a matter of law.

IV. PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT ON THE PURPORTED “GOVERNMENT KNOWLEDGE DEFENSE” SHOULD BE DENIED

In their reply briefs, Plaintiffs simply ignore that evidence of “government knowledge” is not an affirmative defense but rather negates elements of Plaintiffs’ CFCA claims. *See San Francisco Bay Area Rapid Transit Dist. v. Spencer*, No. C 04-04632 SI, 2007 WL 1450350, at *8 (N.D. Cal. May 14, 2007) (“Though it is not an affirmative defense, government knowledge is

¹³ Defendants have cited extensive evidence that California knew that AWP was not an actual average of transaction prices. *See* Joint SOF at ¶¶ 22-40. Defendants have also disputed Plaintiffs’ incomplete rendition of the facts regarding Defendants’ use and understanding of AWP. *See, e.g.,* Sandoz’ Resp. to Pls.’ SOF ¶¶ 6-7. Plaintiffs have not contested that these facts are in dispute. Consequently, material issues of fact remain and summary judgment is inappropriate. *See* *Vacca v. Barletta*, 933 F.2d 31, 35 (1st Cir. 1991) (holding that “[b]ecause material issues of fact are in dispute, the district court correctly denied summary judgment”).

not irrelevant [to a CFCA claim]. It may be used to show that a defendant did not “knowingly” submit, or cause to be submitted, a false claim.”); *U.S. v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n. 8 (5th Cir. 2003) (Jones, J., concurring) (“This defense is inaptly named because it is not a statutory defense to FCA liability but a means by which the defendant can rebut the government’s assertion of the ‘knowing’ presentation of a false claim. Inevitably, the extent of the government’s knowledge is also bound up with whether the claim itself was false.”) Plaintiffs’ motion for summary judgment on a “government knowledge defense” is nothing more than an improper motion *in limine* to exclude admissible evidence from which a jury could reasonably conclude that California had not proven elements of its claims. While Plaintiffs would no doubt prefer this evidence not be presented to the jury, there is simply no basis to argue that this evidence should be not be presented to the jury. Indeed, Plaintiffs have offered absolutely no authority that would support such a drastic step.

Moreover, even if “government knowledge” were an affirmative defense, Defendants have more than adequately demonstrated issues of fact in the record that preclude summary judgment on this issue. Plaintiffs dramatically overstate what constitutes relevant evidence of government knowledge. Plaintiffs have failed to cite *any* authority to support their contention that evidence of government knowledge is only relevant when the evidence demonstrates that Defendants “ma[de] full and timely disclosures of their fraudulently inflated AWP’s, ... [and] the State *formally* and *affirmatively* approved of the alleged wrongful price reporting conduct.”¹⁴ See Plaintiffs’ Reply at 26. Indeed, this is not the standard. Rather, as discussed in Defendants’ Joint Opposition Brief, the relevant questions are whether the government was informed of and

¹⁴ Plaintiffs also erroneously contend that Defendants must make this showing with “undisputed evidence.” See Plaintiffs’ Reply at 26. In making this assertion, Plaintiffs apparently overlooked the fact that *they* have moved for summary judgment on the question of the “government knowledge defense,” not Defendants, and that they bear the burden of producing undisputed evidence to prevail on their motion. If evidence of California’s knowledge is disputed, that merely creates a question of fact for the jury.

implicitly approved of or acquiesced in the relevant conduct. *See, e.g., United States ex rel. Englund v. Los Angeles County*, No. CIV. S-04-282 LKK/JFM, 2006 WL 3097941, at *12 (E.D. Cal. Oct. 31, 2006) (granting summary judgment for defendants because “the Federal government knew what [defendant] was doing and *implicitly* approved of [defendant’s] actions”) (emphasis added); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, ___ F. Supp. 2d ___, Slip. Op. at 25 (D. Mass. Jan. 27, 2010).

The evidence in the record is more than sufficient to raise an issue of fact that California has acquiesced in the reporting of AWP that exceed acquisition costs for policy reasons. Understanding that AWP significantly exceeds acquisition costs, California chose to rely on a modestly discounted AWP as one possible basis for reimbursement because it would give providers a margin above their costs to acquire the drug to ensure that Medi-Cal beneficiaries had adequate access to care. Evidence shows that, in 1997, 1998, and 2000, California elected not to pursue deeper discounts to AWP – even though the deeper discounts would bring reimbursement payments closer in line with providers’ actual costs – out of concern that the lower reimbursement rates would drive providers from the program and impair access to care. *See* Joint SOF at ¶¶ 33, 35, 36. In 2002, when it moved to AWP minus 10 percent, California chose not to set generic reimbursement at AWP minus 40 percent for generic drugs, despite knowing that providers could purchase drugs at 40 to 50 percent below AWP, because of concerns raised by the California Pharmacists Association that the reductions force providers out of the program. *See* Joint SOF at ¶ 52. In 2004, Medi-Cal officials endorsed the move to AWP minus 17 percent, with the understanding that it would pay providers average margins in excess of 180 percent for generic drugs. *See* Joint SOF at ¶¶ 55-57. Most recently, in 2009, Kevin Gorospe, the current Chief of the Medi-Cal Pharmacy Policy submitted an affidavit supporting a

five percent reduction in pharmacy reimbursement payments on the grounds that the ingredient cost portion of California's reimbursement methodology, which still uses AWP minus 17 percent as one possible basis, "is well above pharmacy acquisition cost" and "that any loss on the dispensing fee portion of reimbursement is made up for by a significant profit on Medi-Cal reimbursement for the drug itself." *See* Joint SOF at ¶ 67. At the very least, this evidence creates a question of fact as to whether California acquiesced in Defendants' conduct.

California's attempts to distinguish *United States ex rel. Englund v. Los Angeles County*, 2006 WL 3097941, *12 (E.D. Cal. Oct. 31, 2006) and *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 954 (10th Cir. 2008) are meritless. California contends that *Englund* is distinguishable because the defendant "had never hidden its actions" and that "alleged scheme was well known and public." *See* Plaintiffs' Reply at 30. California apparently ignores the fact that there is no evidence that Defendants ever "hid" their actions from California and that Defendants in fact disclosed pricing information both publicly (in the form of reported WACs) or in some instance directly to California (such as Sandoz's AMP reporting and Dey's disclosures in its price notification letters.) California also ignores the MDL Court's holding that, by 2001, a "perfect storm" of publicly available information existed documenting large spreads between published AWP and providers' costs for drugs. *In re Pharm. Indust. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007).

California contends that *Orenduff* is distinguishable because, in that case, the defendant university had relied on the government's misclassification of the university as a "minority institution" when applying for a federal grant; California contends this case is different because there was no "formal or official pronouncement" from California directing Defendants to report the AWP they reported. *See* Plaintiffs' Reply at 30. This distinction completely ignores the

holding in *Orenduff*, in which the court expressly rejected the argument that the government's knowledge must be coupled with some *express* pronouncement or authorization:

We recognize that in most cases in which summary judgment has been granted on the basis of the government knowledge inference there has been more direct communication between the government and the contractors in the context of an existing contractual relationship – e.g. where the governmental agency, possessing full knowledge of the relevant circumstances arising from such a relationship, authorizes the contractor to make a particular representation that ultimately proves to be false. ... However we conclude that neither the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference. Instead, the focus properly rests upon the depth of the government's knowledge of the facts underlying the allegedly false claim and the degree to which the government invites that claim.

Orenduff, 548 F.3d at 954. Here, California does not dispute that California officials have known throughout the relevant time period that AWP was not a reliable indicator of providers' actual acquisition costs, especially for generic drugs. Yet California has never once attempted to provide any guidance to Defendants as to how AWP should be determined and even today pays claims based on AWPs.

CONCLUSION

For the reasons set forth above, as well as the reasons set forth in Defendants Joint Brief in Opposition to Plaintiffs' Motion for Partial Summary Judgment, Defendants respectfully request that the Court deny the Plaintiffs' Motion for Partial Summary Judgment.

Dated: January 29, 2010

Respectfully Submitted:

KELLEY DRYE & WARREN LLP

/s/Sarah L. Reid

Paul F. Doyle (BBO # 133460)
William A. Escobar (*pro hac vice*)
Sarah L. Reid (*pro hac vice*)
Neil Merkl (*pro hac vice*)
Christopher C. Palermo (*pro hac vice*)
Philip D. Robben (*pro hac vice*)

101 Park Avenue
New York, NY 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Counsel for Defendants Dey, Inc. and Dey, L.P.

KELLEY DRYE & WARREN LLP

/s/Christopher C. Palermo

William A. Escobar (*pro hac vice*)
Neil Merkl (*pro hac vice*)
Christopher C. Palermo (*pro hac vice*)
Philip D. Robben (*pro hac vice*)

101 Park Avenue
New York, NY 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Counsel for Mylan Inc., and Mylan Pharmaceuticals Inc.

WHITE & CASE

/s/Wayne A. Cross

Wayne A. Cross (*pro hac vice*)
1155 Avenue of the Americas
New York, NY 10036
Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Counsel for Sandoz Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on January 29, 2010 a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid

Sarah L. Reid